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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,867	07/03/2001	Banning G. Lary	SYN-053	4123
36822	7590	12/16/2004		
GORDON & JACOBSON, P.C. 65 WOODS END ROAD STAMFORD, CT 06905			EXAMINER MENDEZ, MANUEL A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/898,867	Applicant(s) LARY ET AL.	
	Examiner Manuel Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-25, 30-34 and 41-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 10-25 and 30-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-46 is/are rejected.
- 7) ☒ Claim(s) 47-50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of claims 41-50 in the reply filed on September 13, 2004 is acknowledged. The traversal is on the ground(s) that:

- MPEP Section 811 requires that the restriction requirement be made as soon as the need for it develops”;
- There is no serious burden placed on the Examiner in examining the inventions identified by the examiner; and
- The restriction requirement is improper since the inventions as divided in the restriction requirement are not independent and distinct.

These arguments are not found persuasive because:

- The MPEP does not expressly prohibit an examiner from making a restriction or election requirement after the first office action has been mailed. If the MPEP intended to prohibit restriction requirements or election species after the first office action, it would have expressly prohibited such an action. Since there is no direct prohibition of such said action, the examiner concludes that the action is proper and adequate in view of the present circumstances,
- In response to the “no serious burden argument”, the examiner notes for the record that the required search for the subject matter of the pending claims is extensive and would require a number of “man-hours” that exceed the time allotted to this examiner by the U.S. Patent and Trademark Office to perform an adequate prosecution of this application. The subject matter in this application

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must be searched in class 604, subclasses 65, 96.01, 97.01, 97.02, 98.01, 99.01, 101.01, 101.02, 101.03, 101.04, 101.05, 102.01, 102.02, 102.03, 103.01, 103.02, 103.03, 103.05, 104, 915, 919, and 920. Additionally, the examiner is required to search class 606, subclasses 191, 192, 193, and 194, and furthermore the method claims require search of class 604, subclasses 500 and 508.

Importantly, each of the subclasses listed above contains, on average, more than one hundred patents that have to be carefully reviewed during the prosecution.

Accordingly, based on the size of the search required to properly prosecute this application, it is respectfully requested that applicant becomes aware that there is a serious burden on the examiner; and

- Finally, concerning the “independent and distinct” argument, the examiner notes that the restriction requirement presented six different subclasses for the classification of the broadest claims. Since the subject matter of the claims presents divergent subject matter, the examiner concludes that the restriction requirement is proper.

Claims 1-8, 10-18, 19-21, 22-24, 25, 30-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 13, 2004.

Claim Objections

Claims 47-50 are objected to because of the following informalities:

- Claims 47-50 depend on claims 11, 16, 48, and 48, respectively. Claims 11, 16, and 48 disclose subject matter not within the scope of the elected species.
- In claim 43, the examiner objects to the use of the term "self-expanding". The term "self-expanding" does not include any structural elements to describe this functional term. Accordingly, any inflatable balloon is considered to anticipate this term since said balloons do not require any external structural elements in the catheter to cause their expansion.
- Appropriate correction is required.

Claim Rejections - 35 USC § 103

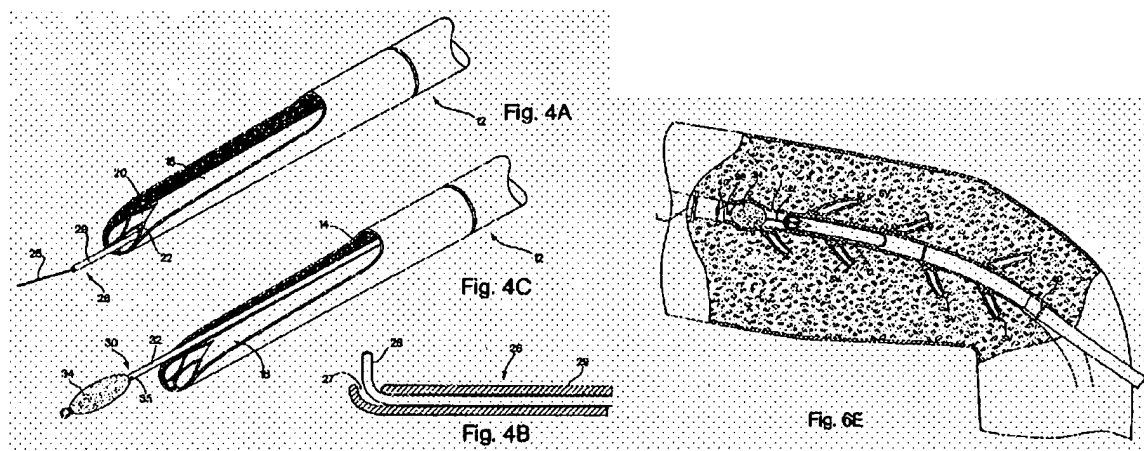
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Biegeleisen, in view of Branco, Knoring, and Kokish, et al.**

The Biegeleisen Patent discloses a venoscope used in the treatment of varicose veins. This patent demonstrates that the steps of delivering a catheter having lumens designed for the infusion of sclerosing agent is conventional in the art. The Biegeleisen Patent does not disclose the use of balloon catheters to enhance the precision in the infusion of agents into a particular area in the body. However, the use of balloon catheters to ensure the proper deployment of an agent into a particular area of the body is conventional as evidenced by the teachings of Branco, Knoring, and Kokish, et al.

The Branco Patent discloses another venoscope enhanced with the capability of deploying balloon catheters into a varicose vein. The figures below demonstrate the conventionality of using inflatable balloon catheters in combination with a scope to precisely infuse an agent to a particular area of the body.



The Branco Patent does not disclose the step of dispensing an agent at a location proximal to the occlusion element. However, balloon catheters having such capability are well known in the art as evidenced by the teachings of Knoring and Kokish, et al. Both patents provide evidence as to the conventionality of catheter designs wherein the agent is infused proximally of the Occlusion element.

Based on the teachings of the cited patents, for a person of ordinary skill in the art, modifying the venoscope disclosed by Biegeleisen with the capability of deploying balloon catheters would have been obvious considering the teachings of Branco. Moreover, modifying the balloon catheter disclosed by Branco with the capability of infusing a fluid agent proximal to a balloon would have been obvious in view of the

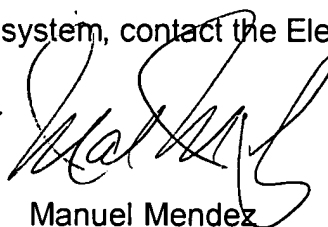
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teachings of Knoring and Kokish, et al. Conclusively, in view of the conventionality of the discussed enhancements, said modifications would have been considered obvious design choices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Manuel Mendez
Primary Examiner
Art Unit 3763

MM